Serial No. 10/047,581

JOHNSON

HRT 287

Please replace paragraph 50 of the published application 20020058995 with the following paragraph

[0050] The mounting ring (85) of the prosthetic valve device is preferably attached at the base of the outside surface of the sleeve. The mounting ring is made of materials that are durable, have been high tensile strength, excellent fatigue characteristics and corrosion resistant (for example, stainless steel, MP35N or elgiloy), and is structured in a compressible architecture such that it can contract upon application and expand upon release of external pressure and still maintain its basic formation. The mounting ring has a generally cylindrical outside surface and a generally cylindrical inside surface comprised of a series of mounting pins (90) to fix the prosthetic valve device at the designated valve situs (FIGS. 13-15). The mounting ring provides endovascular sutureless fixation of the device allowing it to operate autonomously. Referring to FIGS. 13a and 14a, mounting ring 85 includes a first ring 86 and a second ring 87 to which mounting pins 90 are attached. The pins are secured by melding, welding or other connecting methods, at about 30 to about 150 degrees angles to the first ring 86 and second ring 87 of the mounting ring. The composite of angles provides for secure fixation such that the prosthetic valve device can tolerate the degree and directional pressure variations on the valve occurring during the different phases of the cardiac cycle. As uniform pressure is exerted at the inner surface of the mounting ring, as for example, by inflation of the mounting balloon, the mounting ring expands and the pins extend into and secure to the lumen wall. Referring to FIGS. 15a and 15b, mounting pin 90 includes a base 91, a first leg 92 that extends at an angle away from one end of base 91, and a second leg 93 that extends at an angle away from the other end of base 91. First leg 92 has a sharp free 94 and second leg 93 has a sharp free end 95 to assist in ponetrating tissue when the mounting ring is located at the situs, Base 91 can have a first, bent configuration (or transport configuration), depicted in FIGS, 13b and 15a, where mounting ring 85 is in a compressed state for transport to the situs, and a second, straightened configuration (or fasten configuration), depicted in FIGS. 14b and 15b, where mounting ring 85 is in an expanded state for securement to the situs. Referring to FIG. 11, first legs 92 extends from first ring 86 and second legs 93 extends radially outward from second ring 87.

sleeve.

Serial No. 10/047,581

HRT 287

4:25

1-14. (Cancelled)

- 15. (Currently Amended) A valve for implantation at a desired location within a mammal, comprising:
- a flexible sleeve having a proximal end and a distal end; end
 at least one cusp configured to permit blood flow through the at least one cusp in a
 single direction, the valve being capable of insertion to the desired location via a catheter;
 at least one ring attached to the sleeve; and
 at least one fastener extending in a direction radially outward with respect to the
- 16. (Currently Amended) The valve of claim 15, wherein the sleeve has a proximal end and a distal end, and the at least one cusp comprises three cusps attached to at the distal end ef-the sleeve, the three cusps configured to open to permit blood to flow through the distal end when subjected to blood flow through the sleeve from the proximal end to the distal end.
- 17. (Previously Added) The valve of claim 16, wherein the three cusps are configured to open in a distal direction when subjected to blood flow through the sleeve from the proximal end to the distal end.
- 18. (Previously Added) The valve of claim 16, wherein the three cusps are configured to close to prevent blood flow through the sleeve from the distal end to the proximal end.
- 19. (Previously Added) The valve of claim 16, wherein the valve is configured to have an open position that permits blood to flow through the distal end when blood flows through the sleeve from the proximal end to the distal end and a closed position to prevent blood from flowing from the distal end to the proximal end of the sleeve.
- 20. (Previously Added) The valve of claim 19, wherein each of the three cusps has at least one side and each of the three cusps are configured to mate along the at least one side

JOHNSON

Serial No. 10/047,581

HRT 287

with a side of a cusp located adjacent to each of the three cusps when the valve is in the closed position.

- 21. (Currently Amended) The valve of claim 15, wherein the comprising a mounting ring is attached to the elecve at the proximal end:
- 22. (Currently Amended) The valve of claim 1521, wherein the sleeve has an outer surface and the mounting ring is attached to the outer surface.
- (Currently Amended) The valve of claim 1521, wherein the mounting ring is compressible.
- 24. (Currently Amended) The valve of claim 1521, wherein the mounting ring is expandable from a first diameter to a larger, second diameter.
- 25. (Currently Amended) The valve of claim <u>1521</u>, wherein the mounting ring comprises at least one fastener is for attaching at least the sleeve valve at a desired location.
- 26. (Currently Amended) The valve of claim 25, wherein the at least one <u>fastener</u> mounting pin-comprise a series of <u>legs fasteners</u> arranged circumferentially about the mounting-ring.
- 27. (Currently Amended) The valve of claim 25, wherein the mounting ring has a longitudinal axis and the at least one fastener comprises at least one mounting pin attached to the mounting ring, the mounting pin having two ends offset from one another in the longitudinal direction.
- 28. (Previously Added) The valve of claim 27, wherein the two ends of the at least one mounting pin extend radially outward from the mounting ring.

Serial No. 10/047,581

29. (Previously Added) The valve of claim 24, wherein the mounting ring is balloon expandable.

- 30. (Previously Added) The valve of claim 15, wherein the sleeve and cusp are formed of different materials.
- 31. (Previously Added) The valve of claim 15, wherein the at least one cusp comprises one of a homogenic material, an allogenic material and a xenogenic material.
- 32. (Previously Added) The valve of claim 15, wherein the at least one cusp comprises a synthetic material.
- 3332. (Currently Amended) A valve device for implantation at a desired location within a mammal, comprising:
 - a mounting ring expandable from a first diameter to a second diameter; and
- a valve having a proximal end and a distal end, the valve attached to the mounting ring at the proximal end, the valve comprising at least one cusp configured to permit blood flow through the at least one cusp in a single direction.
- 3433. (Currently Amended) The valve device of claim 3332, wherein the valve comprises three cusps attached at a distal end of the valve, the three cusps configured to open and permit blood to flow through the distal end when the cusps are subjected to blood flow through the valve the proximal end to the distal end.
- <u>35</u>34. (Currently Amended) The valve device of claim <u>3433</u>, wherein the valve comprises a sleeve having a first end and a second end, the sleeve attached to the mounting ring on the first end and attached to the three cusps on the second end.
- 3635. (Currently Amended) The valve device of claim 3332, wherein the valve device is capable of being positioned at the desired location via a catheter.

Serial No. 10/047,581

HRT 287

- 3736. (Currently Amended) The valve device of claim 3332, comprising a guidewire for guiding the valve device to a desired location.
- 3837. (Currently Amended) The valve device of claim 3332, comprising a catheter upon having a balloon attached at the distal end of the catheter, the mounting ring and valve being mounted on the balloon.
- 39. (New) The valve device of claim 33, wherein the mounting ring has a transport configuration for transporting the valve device to the desired location and a fasten configuration for fastening the valve device at the desired location, and comprising at least one fastener extending from the mounting ring in a direction radially outward with respect to the sleeve when the mounting ring is in the fasten position.
- 40. (New) The valve device of claim 39, wherein the at least one fastener includes at least one leg having a sharpened distal end.
- 41. (New) The valve device of claim 40, wherein the sharpened distal end is configured to pierce tissue when the valve device is in the fasten configuration at the desired location.
- 42. (New) The valve device of claim 15, wherein the ring has a transport configuration for transporting the valve device to the desired location and a fasten configuration for fastening the valve device at the desired location, and comprising at least one fastener extending from the mounting ring in a direction radially outward with respect to the sleeve when the mounting ring is in the fasten position.
- 43. (New) The valve device of claim 42, wherein the at least one fastener includes at least one leg having a sharpened distal end.
- 44. (New) The valve device of claim 43, wherein the sharpened distal end is configured to pierce tissue when the valve device is in the fasten configuration at the desired location.